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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,428	04/07/2000	Michel F Levesque M D	CEDAR-044526	1086

7590 07/22/2002
Sidley Austin Brown & Wood LLP
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EXAMINER

SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/545,428

Applicant(s)

LEVESQUE M D ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-12 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,5,7-12 and 16-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2002, has been entered. Upon entry of the amendment filed 2/12/02, claims 1-2, 4-5, 7-12, and 16-27 are pending. The request for a 3 month suspension was granted and prosecution on the merits is now resumed with the following restriction requirement:

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1, 2, 5, 8, 9, 11, 12, 18, 22, 25, 26 and 27, drawn to methods of transdifferentiating epidermal basal cells into a cell having one or more morphological, physiological and/or immunological feature of a neural progenitor cell, the transdifferentiated cells and kits comprising said cells, classifiable in class 435, subclasses 325, 366 and 375.
 - II. Claims 1, 2, 4, 5, 7-12, 16, 17, 18, 19-22, 25, 26 and 27, drawn to methods of transdifferentiating epidermal basal cells into a cell having one or more morphological, physiological and/or immunological feature of a neuronal cell, the

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transdifferentiated cells and kits comprising said cells, classifiable in class 435, subclasses 325, 366 and 375.

III. Claims 1, 2, 5, 8, 9, 11, 12, 16, 18-20 and 22-27, drawn to methods of transdifferentiating epidermal basal cells into a cell having one or more morphological, physiological and/or immunological feature of a glial cell, classifiable in class 435, subclass 325, 366 and 375.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects since the claims of Invention I are drawn to generation of transdifferentiated cells having features of neural progenitor cells and the claims of Invention II are drawn to generation of transdifferentiated cells having the features of neuronal cells. Neural progenitor cells and neuronal cells are distinct because they have different chemical, physical, and functional properties. Neural progenitor cells encompass basal cells which have different features from differentiated neuronal cells, such as those of the instant invention defined on page 28 of the instant specification as neuronal cells characterized as having neurites or neuronal processes of a certain length. Applicant further admits on page 12 of the response filed 4/23/02 in related U.S. Patent Application 09/488,491 that neural progenitor cells do not have morphological characteristics of neuron-like cells (neuronal cells) since they do not have the

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neurite-like processes. Since these two cells types, neural progenitor cells and neuronal cells differ in their structure and function, these products are capable of separate manufacture, use or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art).

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects since the claims of Invention II are drawn to generation of transdifferentiated cells having features of neuronal cells and the claims of Invention III are drawn to the generation of transdifferentiated cells having the features of glial cells. Neuronal cells and glial cells are distinct because they have different chemical, physical, and functional properties. Neuronal cells, such as those of the instant invention defined on page 28 of the instant specification as neuronal cells characterized as having neurites or neuronal processes of a certain length, have different features from glial cells, which Applicant describes on page 12 of the response filed 4/23/02 in related U.S. Patent Application 09/488,49 as not having the morphological characteristics of neuron-like cells (neuronal cells) since they do not have the neurite-like processes. Since these two cells types, neuronal cells and glial cells differ in their structure and function, these products are capable of separate manufacture, use or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art).

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5. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects since the claims of Invention I are drawn to generation of transdifferentiated cells having features of neural progenitor cells and the claims of Invention III are drawn to generation of transdifferentiated cells having features of glial cells. While neither neural progenitor cells nor glial cells have neurites characteristic of neuronal cells, they are further distinct from each other because they have different chemical, physical, and functional properties. For instance neural progenitor cells encompass basal cells which are distinct from glial cells that are about 10 times more numerous than neurons, make up about half the weight of the brain and function to keep the neurons healthy and produce new myelin.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and the fact that the search required for each of Group I, II or III is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is further advised that upon election of a group drawn to either of the neural progenitor, neuronal, or glial cell types, the claims will be examined on the merit for

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making the elected type of cell only. Applicant is thus requested to amend the claims so that the claims are drawn only to the administration of growth factors and detection of markers associated with the elected type of cell, either the neuronal progenitor, neuronal or glial cell types.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

A handwritten signature in black ink, appearing to read "M. M. Schmidt". The signature is stylized with a large, looped initial "M" and a cursive "Schmidt".

M. M. Schmidt
July 19, 2002